

## EU Declaration of Conformity

**Manufacturer:**

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

Address: Industrial Park, Jiangdu Bridge, Yangzhou, 225211 Jiangsu P.R. China

Tel: 0086-514-86976213 Fax: 0086-21-51861120

**Authorized Representative:**

Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

**Product Name:** Disposable Surgical Gowns

**Classification:** Class Is, Rule 1, Annex IX, MDD 93/42/EEC

**UMDNS No.:** 11901

**Specification:** lab coats (XS/S/M/L/XL/XXL/XXXL), isolation gowns (XS/S/M/L/XL/XXL/XXXL), surgical gowns (XS/S/M/L/XL/XXL/XXXL), coveralls (XS/S/M/L/XL/XXL/XXXL), scrub suit (XS/S/M/L/XL/XXL/XXXL).

**Conformity Assessment Route:** Annex V

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards, the standards of EN ISO 13485:2016 and BS EN 13795-1:2019. All supporting documentations are retained under the promises of the manufacturer: Jiangsu Medplus Non-woven Manufacturer Co., Ltd. Is exclusively responsible for Declaration of Conformity.

### DIRECTIVES

**General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 5 Sept 2007 concerning medical devices.

**Notified Body:** TÜV Rheinland LGA Products GmbH

**Address of Notified Body:** Tillystraße 2, 90431, Nürnberg, Germany

**Identification number:** CE0197

**(EC) Certificate(s):** DD 2063039-1

**Expire date of the Certificate:** 2024-05-26

**Start of CE marking:** 2020-09-11

**Place, Date of Issue:**

Yangzhou, Jiangsu

09/13/2020

General Manager

(Name and signature or equivalent  
Marking of authorized person)

